

K042172

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Cleo™ 90 Infusion Set

August 10, 2004

OCT 7 - 2004

GENERAL INFORMATION

| | |
|--------------------------------|--|
| Applicant's Name and Address: | Smiths Medical MD, Inc. 1265 Grey Fox Road St. Paul, MN 55112 |
| Contact Person: | David H. Short Director Regulatory and Clinical Affairs |
| Common/Usual Name: | Subcutaneous Infusion Set |
| Proprietary Name: | Cleo™ 90 Infusion Set |
| Equivalence Device Comparison: | Unomedical Comfort Set; Disetronic® Ultraflex™ Set; and the Medtronic MiniMed Sof-Set® |

II. DEVICE DESCRIPTION

The Cleo™ 90 Infusion Set consists of an applicator that contains an adhesive site with cannula and needle and separate extension tubing set with buckle. The infusion set has a standard luer connection. After insertion of the needle and cannula into the subcutaneous tissue, the applicator automatically retracts the needle into the applicator housing providing needle protection. The infusion set buckle attaches to the site allowing infusion of medication through the extension tubing.

III. INTENDED USE OF THE DEVICE

The Cleo 90 Infusion Set is designed for subcutaneous infusion of medication (including insulin) only. The set is not intended for intravenous (IV) infusion or to infuse blood or blood products.

IV. DEVICE COMPARISON

The Cleo 90 Infusion Set was compared to the following similar products: Unomedical, Comfort Set; Disetronic®, Ultraflex™ Set; and the Medtronic MiniMed, Sof-Set®. The Cleo 90 Infusion Set is substantially equivalent to these products by having the identical indication for use, a site with flexible catheter and needle for insertion into the subcutaneous tissue and a separate extension tubing with buckle for attachment to the site. The Unomedical Comfort Set utilizes a rigid needle rather than a flexible cannula. All sets have an adhesive patch that secures the catheter or needle to the skin following placement. The

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Unomedical Comfort Set and Medtronic MiniMed Sof-Set have detachable extension sets, whereas the Disetronic, Ultraflex Set has an integral extension set. For those devices with a flexible cannula, the needle is removed prior to infusion. The Cleo 90 Infusion Set incorporates a needle protection feature that retracts the needle automatically following insertion of the needle and cannula. The needle may also be retracted automatically by the user as well.

V. SUMMARY OF STUDIES**A. Functional Testing**

In-vitro functional testing of the Cleo 90 Infusion Set was conducted.

Biocompatibility testing was performed on the materials of the Cleo 90 Infusion Set.

B. Clinical Studies

Human clinical studies were not deemed necessary to evaluate the safety or effectiveness of the Cleo 90 Infusion Set.

To evaluate the safety and effectiveness of the needle protection feature of the Cleo 90 Infusion Set, a simulated clinical use evaluation was conducted in accordance with the "Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA", December 31, 2002. Individuals who participated in the evaluation included patients who routinely use an insulin pump and infusion set, parents or guardians of patients who insert an infusion set on behalf of a patient, and health care providers who instruct patients and caregivers on the use of infusion pumps and infusion sets. This evaluation determined the needle protection feature operated as intended and no needle sticks or injuries were reported in the evaluation by the participants.

C. Conclusions Drawn from the Studies

The results of the testing conducted indicate the Cleo 90 Infusion Set functioned according to specifications and the materials used in the device are biocompatible. Based on these results, the product is considered acceptable for human use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Mr. David H. Short
Director Regulatory and Clinical Affairs
Smiths Medical MD, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K042172
Trade/Device Name: Cleo 90 Infusion Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: August 10, 2004
Received: August 11, 2004

Dear Mr. Short:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

K042172

Indications for Use

510(k) Number (if known): K042172

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Yvonne Hubbard for Anthony Watson
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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